

510(k) Summary
(21 CFR 807.92)

JUL 12 2013

Manufacturers Name: Rehrig Healthcare Systems

Official Contact: Cindy Meissen
New Market Development Manager
Rehrig Pacific Company
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Consultant: David Olmstead
Radnor Group (for Rehrig Pacific)
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Device Trade Name: SharpsTank™ Reusable Sharps Container

Device Common Name: Reusable sharps container

Device Classification Name: Accessory to hypodermic single lumen needle

Device Classification: Class II
Product Code: 80 MMK
21 CFR 880.5570

Predicate Device: K083511
Industrial Water Solutions, Inc. (Sharpsology)
Enviro Sharp Solutions 3, reusable sharps container

Intended Use:

Rehrig Healthcare Systems SharpsTank™ reusable sharps containers are intended to be used for the collection and transportation of contaminated sharps.

Device Description:

A 4.9 gallon reusable sharps container consisting of the container body, an integrated hinged lid, a torturous path mail chute and flusher insert.

Sharps are deposited into the container by placing the used sharps in the horizontal torturous path mail chute which allows the sharps to drop into the container while keeping fingers and hands away from direct access to the contents in the container. During use the containers can be placed in the optional counter top holder or in the optional wall brackets.

When the contents reach the fill line the flusher and lid are engaged into the final secured position.

Performance Testing:

The FDA has not established a performance standard for this product under Section 514. However, the Rehrig Sharps Tank containers comply with criteria identified in FDA guidance document, OSHA blood borne pathogens regulations and Department of Transportation regulations for transporting regulated medical waste.

Performance Criteria	Test Standard	Results
Life-cycle testing	CSA Z316.6-07, Clause 6.2	Passed
Vibration testing	49 CFR 178.608	Passed
Puncture resistance	ASTM F 2132-01	Passed
Leak resistance	Health Devices, Aug-Sept 1993, ECRI, Vol. 22 Nos. 8-9	Passed
Final closure	49 CFR 178.608 49 CFR 178.603 49 CFR 178.606	Passed
Stability testing	AS/NZS 4261:1994 Appendix D	Passed
Handle strength	AS/NZS 4261:1994 Appendix A	Passed
Fill Capacity	CSA Z316.6-07, Clause 6.2.3 and Rehrig Design Verification	Passed
Drop Test (Impact Resistance Test)	49 CFR 178.603	Passed
Stack testing	49 CFR 178.606	Passed

Summary of Substantial Equivalence:

The design and functional characteristics of the SharpsTank™ and the predicate device are similar as indicated in the predicate device comparison table below. Both the Rehrig device and the predicate device reusable sharps containers are molded from polymeric materials, and conform to national and/or international standards for puncture resistance, leakage, stability, impact resistance, and life cycle testing.

The Rehrig Pacific SharpsTank™ reusable/disposable sharps container introduces no new questions concerning the safety or effectiveness and performs as well as or better than the predicate device. Therefore, the Rehrig Pacific SharpsTank™ is substantially equivalent to the predicate device (K083511).

Predicate Device Substantial Equivalence Comparison

Design Performance Feature	<u>New Rehrig Device</u> SharpsTank™	<u>Predicate Device</u> <u>K083511</u>
Indications for Use	Reusable sharps containers intended to be used for the collection and transport of contaminated sharps and regulated medical waste.	Reusable sharps containers intended to be used for the collection and transport of contaminated sharps and regulated medical waste.
Drop Test (Impact Resistance)	Yes	Yes
Puncture Resistant	Yes	Yes
Overfill detection	Yes	Yes
Leak proof on sides and bottom	Yes	Yes
Closable	Yes	Yes
Stable	Yes	Unknown
Access	Torturous path	Torturous path
Mounting accessory	Available	Available
Handling	Handle on the closed lid	Handles on the sides of the container
Capacity	4.9 gallon	3 gallon
Orange label with "BIOHAZARD" warning	Yes	Yes
Life-cycle testing	Yes	Yes
Life-cycle tracking	Bar code on label	Bar code on label
Target Population	Healthcare professionals	Healthcare professionals
Reusable	Yes	Yes
Material	Plastic	Plastic



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

July 12, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Rehrig Pacific Company
C/O Mr. David Olmstead
The Radnor Group
614 Hunters Lane
BRENTWOOD TN 37027

Re: K131087

Trade/Device Name: SharpsTank™ Reusable Sharps Container

Regulation Number: 21 CFR 880.5570

Regulation Name: Hyperdermic single lumen needle

Regulatory Class: II

Product Code: MMK

Dated: April 26, 2013

Received: April 30, 2013

Dear Mr. Olmstead:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Tejasri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: Not yet assigned K131087

Device Name: SharpsTank™ Reusable Sharps Container

Device Part (Model) Number: Model TS

Indications for Use:

Rehrg Healthcare's reusable 4.9 gallon sharps containers are intended to be used for the collection and transportation of used medical sharps. The containers are intended to be used by healthcare workers in hospitals, clinics, physician offices, dental offices, laboratories, veterinarian offices, and other areas where sharps disposal is needed.

Empty Weight:

5.66 lbs.

Dimensions:

Assembled Container: 15.14"L x 7.48"W x 19.96"H

Color: Transparent tan with red/orange red label and contrasting Biohazard Symbol

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131087